10/551182

Atty. Dkt. No. 081356-0251

JC20 Recapet/PTO 29 SEP 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Takashi ISHIHARA

Title:

PURIFICATION OF HUMAN MONOCLONAL

ANTIBODY AND HUMAN POLYCLONAL ANTIBODY

Int'l. Appln. No.

PCT/JP2004/003425

Int'l. Filing Date:

March 15, 2004

Examiner:

Unassigned

Art Unit:

Unassigned

UNDER 37 CFR §1.56

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

Atty. Dkt. No. 081356-0251

JC20 Rec'd PCT/PTO 29 SEP 2005

RELEVANCE OF EACH DOCUMENT

The documents being cited in the attached PTO/SB/08 were cited as being relevant during the prosecution of the corresponding international application. A copy of the International Search Report is attached setting forth the portion of the documents considered relevant by the examiner. A copy of the cited references listed in the Search Report is not being submitted herewith.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date: 29 September 2005

FOLEY & LARDNER LLP Customer Number: 22428

Telephone:

(202) 672-5404

Facsimile:

(202) 672-5399

Stephen A. Bent Attorney for Applicant

Registration No. 29,768

JC20 Rec'd PCT/PTO 2 9 SEP 2005 (08-00) Approved for use through 10/31/2002. OMB 0651-0031

081356-0251

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Substitute for form 1449B/PTO Complete if Known INFORMATION DISCLOSURE **Application Number** Unassigned STATEMENT BY APPLICANT September 29, 2005 Filing Date First Named Inventor Takashi ISHIHARA Date Submitted: September 29, 2005 Group Art Unit Unassigned **Examiner Name** Unassigned (use as many sheets as necessary)

Attorney Docket Number

| | | | · · · · · · · · · · · · · · · · · · · | U.S. PATENT DOCUMENTS | - | |
|-----------------------|------|----------------------|---|--|------------------------------|---|
| Examiner Initials* | Cite | U.S. Patent Document | | Name of Patentee or Applicant of Cited | Date of Publication of | Pages, Columns, Lines, Where Relevant Passages or Relevant |
| | No.1 | Number | Kind Code ² (<i>if</i> known) | Document · | Cited Document MM-DD-YYYY | Figures Appear |
| | | | | | | |
| | | | | | | |
| | | | | | | |

| Examiner Initials* | Cite No.1 | Foreign Patent Document | | Name of Patentee or Applicant of Cited Documents | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | 16 |
|-----------------------|--------------|--|--|--|--|--|----|
| | | Office ³ Number ⁴ Kind Code ⁵ (<i>if known</i>) | | | | | |
| | A1 | JP 5-310780 A | | Toa Gosei Chem. Ind. Ltd. | 11/22/1993 | | |
| | A2 | WO 99/64462 A1 | | Statens Serum Institute | 12/16/1999 | | |
| | A3 | WO 01/64711 A1 | | Kyowa Hakko Kogyo Co., Ltd. | 9/7/2001 | | |
| | A4 | WO 96/33208 A1 | | Genentech, Inc. | 10/24/1996 | | T |

| | | NON PATENT LITERATURE DOCUMENTS | | |
|-----------------------|--------------|--|------------------------------|--|
| Examiner Initials* | Cite No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | country where T ⁶ | |
| | A5 | B.J. Moellering et al., "Separating clinical-grade chimeric antibodies from serum-derived immunoglobulins", BioPharm, (1990) 3(1); pp. 34-38 particularly, Table 1, Materials & Methods. | | |
| | A6 | H. Leibl, et al., "Separation of polysaccharide-specific human immunoglobulin G subclasses using a protein A superose column with a pH gradient elution system", Journal of Chromatography, June 4, 1993, 639(1); pp. 51-56, particularly Figs. 1-4; table 1. | | |
| - | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

| Examiner Signature | Date Considered | |
|-----------------------|--------------------|--|

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Sheet

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.